

## ACE Inhibitors, Angiotensin Receptor Blockers, Beta-Blockers

### LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?  
Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug-to-drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
 Document clinically compelling information
  
2. The requested medication may be approved if both of the following are true:
  - If there has been a therapeutic failure of no less than a **one-month trial** of at least **one** medication **within the same class** not requiring prior approval
  - The requested medications corresponding generic (if a generic is available and covered by the State) has been attempted and failed or is contraindicated

### ADDITIONAL INFORMATION TO AID IN FINAL DECISION

If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. Document details. This medication should be reviewed for need at each request for reauthorization.

#### Angiotensin Receptor Blockers and Combinations

| Preferred Drugs - No PA Required        | Non-preferred Drugs - PA Required |
|---|-----------------------------------|
| Cozaar® ( <i>Losartan Potassium</i> ) * | Atacand®                          |
| Diovan®                                 | Atacand HCT®                      |
| Diovan HCT®                             | Avalide®                          |
| Hyzaar®                                 | Avapro® ( <i>Irbesartan</i> ) *   |
|   | Benicar®                          |
|   | Benicar HCT®                      |
|   | Micardis®                         |
|   | Micardis HCT®                     |
|   | Teveten®                          |
|   | Teveten HCT®                      |

Drug lists continued on next page.

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## ACE Inhibitors, Angiotensin Receptor Blockers, Beta-Blockers (continued page 2)

### ACE Inhibitors and Combinations

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required     |
|----------------------------------|---------------------------------------|
| Benazepril                       | Accupril®                             |
| Benazepril/HCTZ                  | Accuretic®                            |
| Captopril                        | Aceon®                                |
| Captopril/HCTZ                   | Altace Capsule® ( <i>Ramipril</i> ) * |
| Enalapril                        | Altace Tablet®                        |
| Enalapril/HCTZ                   | Capoten®                              |
| Lisinopril                       | Capozide®                             |
| Lisinopril/HCTZ                  | Fosinopril                            |
|                                  | Fosinopril/HCTZ                       |
|                                  | Lotensin®                             |
|                                  | Lotensin HCT®                         |
|                                  | Mavik®                                |
|                                  | Moexipril                             |
|                                  | Monopril®                             |
|                                  | Monopril HCT®                         |
|                                  | Moexipril/HCTZ                        |
|                                  | Prinivil®                             |
|                                  | Prinzide®                             |
|                                  | Quinapril                             |
|                                  | Quinaretic®                           |
|                                  | Trandolapril                          |
|                                  | Uniretic®                             |
|                                  | Univasc®                              |
|                                  | Vaseretic®                            |
|                                  | Vasotec®                              |
|                                  | Zestoretic®                           |
|                                  | Zestril®                              |

### ACE or ARB plus Calcium Channel Blocker Combinations

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Lotrel®                          | Amlodipine/Benazepril             |
|                                  | Azor®                             |
|                                  | Exforge®                          |
|                                  | Lexxel®                           |
|                                  | Tarka®                            |
|                                  | Teczem®                           |

Drug lists continued on next page.

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## ACE Inhibitors, Angiotensin Receptor Blockers, Beta-Blockers (continued page 3)

### Beta Blockers and Combinations

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Acebutaolol                      | Betapace®                         |
| Atenolol                         | Betapace AF®                      |
| Atenolol/Chlorthalidone          | Blockadren®                       |
| Betaxolol                        | Cartrol®                          |
| Bisoprolol Fumarate              | Coreg®                            |
| Bisoprolol/HCTZ                  | Coreg CR®                         |
| Carvedilol                       | Corgard®                          |
| Labetalol                        | Corzide®                          |
| Metoprolol/HCTZ                  | Inderal®                          |
| Metoprolol tartrate              | Inderal LA®                       |
| Nadolol                          | Inderide®                         |
| Pindolol                         | Innopran XL®                      |
| Propranolol Solution             | Kerlone®                          |
| Propranolol                      | Levitol®                          |
| Propranolol/HCTZ                 | Lopressor®                        |
| Sorine®                          | Lopressor HCT®                    |
| Sotalol                          | Metoprolol succinate              |
| Sotalol AF                       | Nadolol/Bendroflumethiazide       |
| Timolol Maleate                  | Normodyne®                        |
|                                  | Sectral®                          |
|                                  | Tenoretic®                        |
|                                  | Tenormin®                         |
|                                  | Timolide®                         |
|                                  | Toprol XL®                        |
|                                  | Trandate®                         |
|                                  | Zebeta®                           |
|                                  | Ziac®                             |

### TOPROL XL®: Authorize if any of the following are true

- Toprol XL® 25mg po qd will be authorized as it would not be feasible to promote metoprolol 12.5mg po BID. Toprol XL® 25mg will be authorized with a quantity limit of 45 tablets per 30 days.
- Doses >37.5 mg Toprol XL® po qd will be offered a change to metoprolol in a total daily dose divided by two and dosed BID
- If patient compliance is questioned or compromised by change, then the Toprol XL® will be authorized

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Antibiotics: Cephalosporins, Macrolides, Quinolones****LENGTH OF AUTHORIZATIONS:** for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?  
Acceptable reasons include:  
Allergy to product formulation (i.e. dyes, fillers). If an allergy to drug class, should question medication request.  
Contraindication to or drug-to-drug interaction with medications not requiring prior approval  
History of unacceptable/toxic side effects to medications not requiring prior approval  
Document clinically compelling information
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication. Document details.
  - Note diagnosis and any culture and sensitivity reports
3. If there has been a therapeutic failure to no less than a **three-day** trial of **one** medication within the same not requiring prior approval, then may approve the requested medication. Document details.

**ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

If the patient requires a prior authorized medication based on a specific medical need that is not covered by the FDA indications of the preferred medications, then allow the non-preferred medication. This information should be reviewed at each request for reauthorization.

| Preferred Drugs - No PA Required    | Non-preferred Drugs - PA Required |
|-------------------------------------|-----------------------------------|
| <b>Second Generation Quinolones</b> |                                   |
| Ciprofloxacin                       | Cipro®                            |
| Ciprofloxacin Suspension            | Cipro® Suspension                 |
| Ofloxacin                           | Cipro XR®                         |
|                                     | Ciprofloxacin XR                  |
|                                     | Floxin®                           |
|                                     | Maxaquin®                         |
|                                     | Noroxin®                          |
| <b>Third Generation Quinolones</b>  |                                   |
| Avelox®                             | Factive®                          |
| Avelox ABC PACK®                    | Levaquin®                         |
|                                     | Levaquin Suspension ®             |
|                                     | Zagam®                            |

Drug lists continued on next page.

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Antibiotics – Cephalosporins, Macrolides, Quinolones (page 2)**

| Preferred Drugs - No PA Required        | Non-Preferred Drugs - PA Required |
|---|-----------------------------------|
| <b>Second Generation Cephalosporins</b> |                                   |
| Cefaclor Capsule                        | Ceclor®                           |
| Cefaclor suspension                     | Ceclor® CD                        |
| Cefaclor ER                             | Ceftin® tablets                   |
| Ceftin® suspension                      | Cefzil®                           |
| Cefprozil                               | Cefzil® Suspension                |
| Cefprozil Suspension                    |                                   |
| Cefuroxime tablets                      |                                   |
| Lorabid®                                |                                   |
| Lorabid® Suspension                     |                                   |
| Ranicl®                                 |                                   |
| <b>Third Generation Cephalosporins</b>  |                                   |
| Cedax Capsule®                          | Cefpodoxime                       |
| Cedax® Suspension                       | Cefdinir Capsule                  |
| Omnicef® Capsules                       | Cefdinir Suspension               |
| Omnicef® Suspension                     | Suprax Susp®                      |
| Spectracef®                             | Vantin®                           |
|   | Vantin Susp®                      |
| <b>Macrolides</b>                       |                                   |
| Azithromycin                            | Biaxin®                           |
| Azithromycin Packet                     | Biaxin® Suspension                |
| Azithromycin Suspension                 | Biaxin XL®                        |
| Clarithromycin                          | Dynabac®                          |
| Clarithromycin ER                       | E.E.S.®                           |
| Clarithromycin Suspension               | ERYC®                             |
| Erythrocin stearate                     | Eryped®                           |
| Erythromycin base                       | Ery-tab®                          |
| Erythromycin ethylsuccinate             | Ketek® **                         |
| Erythromycin estolate suspension        | PCE®                              |
| Erythromycin stearate                   | Zithromax® Suspension             |
| Erythromycin with sulfisoxazole         | Zithromax®                        |
|   | ZMAX® suspension                  |

\*\* To receive a PA for Ketek®,

- o A specific Ketek PA request form must be completed and faxed or mailed to First Health Services with the physician's signature. By signing this request, the physician accepts understanding of the contraindications and warnings with the use of Ketek and acknowledges that the benefits of the drug outweigh the possible risks. A copy of the PA form is available at [http://www.dmas.virginia.gov/pharm-pdl\\_program.htm](http://www.dmas.virginia.gov/pharm-pdl_program.htm) or at <http://virginia.fhsc.com>. The PA may also be completed online at: <https://webpa.fhsc.com/webpa>.
- o Recipient must be 18 or over and can only be approved for an FDA indication

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Antifungals (Oral) for Onychomycosis

**LENGTH OF AUTHORIZATIONS:** For the duration of the prescription (up to 6 months)

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

If the patient has a serious illness that causes them to be immunocompromised (i.e. AIDS, cancer, etc.) then may approve the requested medication.

### **ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

1. If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital or other similar location, or if the patient has just become Medicaid eligible and is already on a course of treatment with a medication requiring prior approval, then may approve the requested medication.
2. If the request is for a diagnosis other than fungal infection, please refer to a clinical pharmacist.

### **Sporanox**

If Sporanox is requested for any other FDA approved indication (other than onychomycosis), then approve for 6 months or the duration of the prescription.

Indications: Aspergillosis, Candidiasis (oral or esophageal), Histoplasmosis, Blastomycosis, empiric treatment of febrile neutropenia

Transfer requests for any other diagnosis to a clinical pharmacist.

### **ORAL ANTIFUNGALS USED FOR ONYCHOMYCOSIS**

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Terbinafine                      | Itraconazole                      |
|                                  | Lamisil®                          |
|                                  | Sporanox® Solution                |
|                                  | Sporanox® Capsules                |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Low Sedating Antihistamines: Second Generation

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. If there has been a therapeutic failure after a course of treatment (e.g., one month for allergic rhinitis) with one product not requiring prior approval, then may approve the requested medication.

Document details

### Second Generation Antihistamines and Combinations

| Preferred Drugs - No PA Required                  | Non-preferred Drugs - PA Required            |
|---|--|
| Claritin OTC®                                     | Allegra®                                     |
| Claritin OTC® Syrup                               | Allegra Suspension ®                         |
| Claritin Tablets- Rapids OTC®                     | Allegra-D 12 hr®                             |
| Claritin-D 24hr OTC®                              | Allegra-D 24 hr®                             |
| Claritin-D 12 hr OTC®                             | Clarinet Table® <sup>*</sup> (Desloratadine) |
| Loratadine tablet (represents all OTC names)      | Clarinet Tablet Rapids®                      |
| Loratadine Tab- Rapids (represents all OTC names) | Clarinet® syrup                              |
| Loratadine Syrup (represents all OTC names)       | Clarinet- D® 24 hr                           |
| Loratadine D 24hr (represents all OTC names)      | Clarinet- D® 12 hr                           |
| Loratadine D 12 hr (represents all OTC names)     | Clarinet-D® - Rx forms                       |
|   | Clarinet® - Rx forms                         |
|   | Fexofenadine                                 |
|   | Fexofenadine/PSE                             |
|   | Xyzal®                                       |
|   | Zyrtec Tablet®                               |
|   | Zyrtec Tablet Chew®                          |
|   | Zyrtec® syrup no PA required < 2yrs of age   |
|   | Zyrtec-D®                                    |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Antimigraine Medications: Serotonin Receptor Agonists “Triptans”

**LENGTH OF AUTHORIZATIONS:** 6 months

1. Is there any reason the patient cannot be switched to a non-prior approved medication?

Acceptable reasons include:

- Allergy to **one** of the non-prior approved products
- Contraindication to all non-prior approved product(s)
- History of unacceptable side effects to **one** of the non-prior approved product(s)

Document clinically compelling information

2. Has the patient had therapeutic trial of **one** non-prior authorized drug that failed? If so, document and allow the prior authorized medication.

### **CLINICAL CONSIDERATIONS:**

Prior Authorization will not be given for prophylactic therapy of migraine headache unless the patient has exhausted or has contraindications to all other “controller” migraine medications (i.e., beta-blockers, calcium channel blockers, etc) and the physician and patient are aware of the adverse risk potential.

### **Triptans**

| Preferred Drugs - No PA Required           | Non-preferred Drugs - PA Required |
|--|-----------------------------------|
| Imitrex Cartridge®                         | Amerge®                           |
| Imitrex Nasal®                             | Axert®                            |
| Imitrex Pen Kit®                           | Frova®                            |
| Imitrex Tablets® (Sumatriptan Succinate) * | Relpax®                           |
| Imitrex Vial®                              | Zomig Tablets®                    |
| Maxalt®                                    | Zomig nasal spray®                |
| Maxalt MLT®                                | Zomig ZMT®                        |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*



## Antivirals: Herpes

### LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable; changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there has been a therapeutic **failure of a trial of at least one medications** not requiring prior approval, then may approve the requested medication.

### Antivirals: Herpes

| Preferred Drugs - No PA Required      | Non-preferred Drugs - PA Required |
|---------------------------------------|-----------------------------------|
| Acyclovir Tablets                     | Famciclovir                       |
| Acyclovir Susp                        | Zovirax Susp <sup>®</sup>         |
| Famvir <sup>®</sup>                   | Zovirax Tablet <sup>®</sup>       |
| Valtrex <sup>®</sup> (Valacyclovir) * |                                   |

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## Antivirals: Influenza

### LENGTH OF AUTHORIZATIONS:

- For diagnosis of influenza the authorization is for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable; changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there has been a therapeutic **failure of a trial of at least one medications** not requiring prior approval, then may approve the requested medication.

### Antivirals: Influenza

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Amantadine                       | Flumadine®                        |
| Amantadine Syrup                 | Flumadine Syrup®                  |
| Relenza Disk®                    | Symmetrel                         |
| Rimantadine                      | Symmetrel Susp                    |
| Tamiflu®                         |                                   |
| Tamiflu Susp®                    |                                   |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Antivirals: Interferon for Hepatitis C

### LENGTH OF AUTHORIZATIONS:

SEE BELOW

#### **Clinical PA for initial 16 week PA:**

1. Initial approval periods should be limited to 16-weeks and viral titer should be obtained at week 12 of therapy.

#### **Clinical PA for established HCV reactors:**

2. Therapy is approvable for a total of 24 weeks in patients that are HCV genotypes 2 or 3 who have achieved a virologic response (either undetectable HCV RNA [ $<50$  IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment.
3. Therapy is approvable for total of 48 weeks in HCV genotype 1 or 4 patients who have achieved a virologic response (either undetectable HCV RNA [ $<50$  IU/mL] or at least a 2-log drop in HCV RNA titer from baseline) at 12 weeks of treatment.
4. If patients fail to achieve a virologic response by 12 weeks, further treatment is not indicated.

### PDL PA

1. Is there any reason the patient cannot be started on a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to product formulation (i.e. dyes or fillers). If an allergy to drug class, should question medication request.
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. Has there been a therapeutic failure after a reasonable therapeutic trial with use of **one** of the non-prior authorized agents? Document the details, and forward all of these requests to a clinical pharmacist.

#### **Additional Information:**

1. **Copegus®** and **Rebetol®** are oral ribavirins. Oral ribavirin therapy is not effective for the treatment of chronic hepatitis C viral infection and should not be used alone for this indication.
2. **Pegasys®** and **PEG-Intron®** are pegylated Interferons.

#### **Antivirals: Interferon**

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Pegasys                          |                                   |
| Pegasys Conv.Pack                |                                   |
| Peg-Intron                       |                                   |
| Peg-Intron Redipen               |                                   |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Beta-Adrenergic Agents

### LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. If there has been a therapeutic failure to no less than a **two-week** trial of at least **one** medication not requiring prior approval **within the same class and formulation**. (ie nebulizers for nebulizers)

Document details

### ADDITIONAL INFORMATION

Patients experience cardiac and central nervous system side effects (i.e. tachycardia, agitation) more often.

#### Beta Adrenergic Agents

| Preferred Drugs - No PA Required                              | Non-preferred Drugs - PA Required |
|---|-----------------------------------|
| Short Acting and Combination Metered Dose Inhalers or Devices |                                   |
| Albuterol   | Proventil <sup>®</sup>            |
| Alupent MDI   | Ventolin <sup>®</sup>             |
| Combivent <sup>®</sup> MDI                                    | Albuterol HFA                     |
| Maxair <sup>®</sup> Autohaler                                 | Proair <sup>®</sup> HFA           |
| Proventil <sup>®</sup> HFA                                    |                                   |
| Ventolin <sup>®</sup> HFA                                     |                                   |
| Xopenex <sup>®</sup> HFA                                      |                                   |
| Long Acting Metered Dose Inhalers or Nebulizers               |                                   |
| Foradil <sup>®</sup>  | Brovana <sup>®</sup>              |
| Serevent Diskus <sup>®</sup>                                  | Perforomist <sup>®</sup>          |
| Short Acting Nebulizers                                       |                                   |
| Accuneb <sup>®</sup> pediatric dosing, premixed nebs          | Proventil <sup>®</sup>            |
| Albuterol Sulfate <i>premix &amp; concentrate</i>             |                                   |
| Metaproterenol  |                                   |
| Xopenex <sup>®</sup>  |                                   |

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**Calcium Channel Blockers:**  
***Dihydropyridine Calcium Channel Blockers and***  
***Non-dihydropyridine Calcium Channel Blockers***

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. The requested medication may be approved if both of the following are true:

- If there has been a therapeutic failure to no less than a one-month trial of at least one medication within the same class not requiring prior approval
- The requested medications corresponding generic (if a generic is available and covered by the state) has been attempted and failed or is contraindicated

**CLINICAL NOTES**

There are two main classes of Calcium Channel Blockers (each with different actions on the peripheral vasculature and cardiac tissue):

1. Dihydropyridine Calcium Channel Blockers (DHPCCB)
2. Non-Dihydropyridine Calcium Channel Blockers (NDHPCCB)

Vascor is in its own third class of Calcium Channel Blockers and not included under PA requirements on the VA PDL at this time.

See next page for specific drug lists.

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**Calcium Channel Blockers:**  
***Dihydropyridine Calcium Channel Blockers and***  
***Non-dihydropyridine Calcium Channel Blockers***  
**(Continued)**

**Calcium Channel Blockers**

| <b>Preferred Drugs - No PA Required</b>             | <b>Non-preferred Drugs - PA Required</b> |
|---|--|
| <b>Dihydropyridine Calcium Channel Blockers</b>     |  |
| Afedítab CR®  | Adalat CC®                               |
| Dynacirc CR®  | Amlodipine                               |
| Felodipine ER                                       | Cardene®                                 |
| Nicardipine   | Cardene SR®                              |
| Nifediac CC®  | Dynacirc®                                |
| Nifedical XL®                                       | Procardia®                               |
| Nifedipine  | Procardia XL®                            |
| Nifedipine ER                                       |  |
| Nifedipine SA                                       |  |
| Norvasc®  |  |
| Plendil®  |  |
| Sular®  |  |
| <b>Non-Dihydropyridine Calcium Channel Blockers</b> |  |
| Cartia XT®  | Calan®                                   |
| Diltia XT®  | Calan SR®                                |
| Diltiazem   | Cardizem®                                |
| Diltiazem ER q 24hr dose                            | Cardizem CD®                             |
| Diltiazem ER q 12hr dose                            | Cardizem LA®                             |
| Diltiazem XR  | Cardizem SR®                             |
| Taztia XT®  | Covera HS®                               |
| Verapamil   | Dilacor XR®                              |
| Verapamil SA  | Diltiazem SR q 12hr dose                 |
| Verapamil 24hr pellets                              | Isoprin SR®                              |
|   | Isradipine ®                             |
|   | Tiazac®                                  |
|   | Verelan®                                 |
|   | Verelan PM®                              |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Central Nervous System Stimulants/ADHD Medications

**LENGTH OF AUTHORIZATION:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. If there has been a therapeutic failure to no less than a **one-month trial** of at least **one** medication not requiring prior approval, then may approve the requested medication. Document details.

3. The patient must have failed the generic product (if covered by the State) before the brand is authorized.

4. If the patient requires a prior authorized medication based on a specific medical need that is not covered by the FDA indications of the preferred medications, then allow the non-preferred medication. This should be reviewed for need at each request for reauthorization.

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| <b>Amphetamine Products</b>      |                                   |
| Adderall XR <sup>®</sup>         | Adderall <sup>®</sup>             |
| Amphetamine Salts combo          | Desoxyn <sup>®</sup>              |
| Dextroamphetamine                | Dexedrine <sup>®</sup>            |
| Dextroamphetamine SR             | Dexedrine spansule <sup>®</sup>   |
| Dextroamphetamine Solution       |                                   |
| Dextrostat <sup>®</sup>          |                                   |
| <b>Methylphenidate Products</b>  |                                   |
| Concerta <sup>®</sup>            | Daytrana <sup>™</sup> Transdermal |
| Focalin <sup>®</sup>             | Dexmethylphenidate                |
| Focalin XR <sup>®</sup>          | Ritalin <sup>®</sup>              |
| Metadate CD <sup>®</sup>         | Ritalin SR <sup>®</sup>           |
| Metadate ER <sup>®</sup>         | Vyvanse <sup>®</sup>              |
| Methylin <sup>®</sup>            |                                   |
| Methylin chew <sup>®</sup>       |                                   |
| Methylin ER <sup>®</sup>         |                                   |
| Methylin solution <sup>®</sup>   |                                   |
| Methylphenidate                  |                                   |
| Methylphenidate SR               |                                   |
| Ritalin LA <sup>®</sup>          |                                   |
| <b>Miscellaneous Products</b>    |                                   |
| Strattera <sup>®</sup>           | Provigil <sup>®</sup>             |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

(Nuvigil) \*

## Corticosteroids: Inhaled and Nasal Steroids

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable—patient has had an ER visit or at least two hospitalizations for asthma in the past thirty days—changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there have been therapeutic failures to no less than **one-month** trials of at least **two** medications not requiring prior approval, then may approve the requested medication.

Document details

### **ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

1. If a medication requiring prior approval was initiated in the hospital, and then may approve the requested medication.

Document details

2. If the patient is a child <13 years old or a patient with a significant disability, and unable to use an inhaler which does not require prior approval, or is non-compliant on an inhaler not requiring prior approval because of taste, dry mouth, infection; then may approve the requested medication.

Document details

See next page for specific drug lists.

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*



**Corticosteroids:  
Inhaled and Nasal Steroids  
(Continued page 2)**

**Inhaled Corticosteroids**

| Preferred Drugs - No PA Required                                 | Non-preferred Drugs - PA Required |
|--|-----------------------------------|
| <b>Metered Dose Inhalers</b>                                     |                                   |
| Aerobid <sup>®</sup>   | Flovent Rotadisk <sup>®</sup>     |
| Aerobid M <sup>®</sup>   | Flovent <sup>®</sup>              |
| Asmanex <sup>®</sup>   | Pulmicort Flexhaler <sup>®</sup>  |
| Azmacort <sup>®</sup>  |                                   |
| Flovent HFA <sup>®</sup>   |                                   |
| Flovent Diskus <sup>®</sup>                                      |                                   |
| QVAR <sup>®</sup>  |                                   |
| <b>Nebulizer Solution</b>  |                                   |
| Pulmicort Respules <sup>®</sup>                                  |                                   |
| <b>Combination Products (Glucocorticoid and Beta Adrenergic)</b> |                                   |
| Advair Diskus  | Symbicort <sup>®</sup>            |
| Advair HFA   |                                   |

**Nasal Steroids**

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Flunisolide                      | Allemist <sup>®</sup>             |
| Fluticasone                      | Beconase AQ <sup>®</sup>          |
| Nasacort AQ <sup>®</sup>         | Flonase <sup>®</sup>              |
| Nasonex <sup>®</sup>             | Nasacort <sup>®</sup>             |
|                                  | Nasarel <sup>®</sup>              |
|                                  | Rhinocort AQUA <sup>®</sup>       |
|                                  | Tri-Nasal <sup>®</sup>            |
|                                  | Veramyst <sup>®</sup>             |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## COPD: Anticholinergics

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable—patient has had an ER visit or at least two hospitalizations for asthma in the past thirty days—changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there have been therapeutic failures to no less than **one-month** trials of at least **two** medications not requiring prior approval, then may approve the requested medication.

Document details

### COPD Anticholinergics

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Atrovent AER <sup>®</sup>        | Duoneb <sup>®</sup>               |
| Atrovent HFA <sup>®</sup>        | Ipratropium/Albuterol             |
| Combivent <sup>®</sup> MDI       |                                   |
| Ipratropium Bromide Solution     |                                   |
| Spiriva <sup>®</sup>             |                                   |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## COX-2 Inhibitors

### Clinical edit

**LENGTH OF AUTHORIZATIONS:** 1 year

The preferred product may be approved for patients if one of the following is true:

- If there has been a therapeutic trial and failure on a minimum of two (2) different non-COX2 NSAIDs
- Concurrent use of anticoagulants (warfarin or heparin)
- Chronic use of oral corticosteroids
- Concurrent use of methotrexate
- History of previous GI bleed or conditions associated with GI toxicity risk factors (i.e., PUD, GERD, etc.)
- If there is a specific indication for medication requiring prior approval, for which medications not requiring prior approval are not indicated, then document details and refer caller to a clinical pharmacist
- Patients with a diagnosis of familial adenomatous polyposis (FAP) presenting with a prescription for celecoxib (Celebrex®) may be approved without any risk factors or trials on NSAIDs.

### CRITICAL INFORMATION TO CONSIDER

1. Selective cyclooxygenase-2 (COX-2) inhibitors are known to inhibit the production of vascular prostacyclin (PGI<sub>2</sub>), an inhibitor of platelet aggregation and a vasodilator. Unlike conventional non-steroidal anti-inflammatory drugs, COX-2 inhibitors do not reduce the endogenous production of thromboxane A<sub>2</sub>, a potent platelet activator and aggregator, thereby causing a potentially prothrombotic cascade of events that could lead to a significant increase in the risk for thrombotic cardiovascular events (myocardial infarction, occlusive stroke) in patients receiving celecoxib therapy. **Therefore, it is advisable to exercise caution when prescribing celecoxib, a COX-II inhibitors to patients with a higher risk of cardiovascular disease.**
2. If the patient is allergic to one NSAID or aspirin, the patient may be allergic to other NSAIDs.
3. If allergic to sulfonamides, a patient should not receive Celebrex®.

### Cox-2 Inhibitors

| Preferred Drugs - PA Required | Non-preferred Drugs - N/A |
|-------------------------------|---------------------------|
| Celebrex®                     |                           |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Electrolyte Depleters

### LENGTH OF AUTHORIZATIONS: 1 year

2. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable; changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there has been a therapeutic **failure to at least a one-month trial of at least one medication** not requiring prior approval, then may approve the requested medication.

### Electrolyte Depleters

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Fosrenol <sup>®</sup>            |                                   |
| Phoslo <sup>®</sup>              |                                   |
| Renagel <sup>®</sup>             |                                   |

---

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Gastrointestinals: Histamine -2 Receptor Antagonists (H-2 RA)****LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable—patient has had an ER visit or at least two hospitalizations for asthma in the past thirty days—changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there has been a therapeutic failure to no less than a **one-month trial** of at least **one** medication not requiring prior approval, then may approve the requested medication.

Document details

3. If a medication requiring prior approval was initiated in the hospital for the treatment of a condition such as a GI bleed, and then may approve the requested medication.
4. Treatment of warts is not an FDA approved diagnosis or indication for Tagamet / cimetidine and a PA will not be approved for this diagnosis or indication.

**H2 Receptor Antagonists**

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required                                  |
|----------------------------------|--|
| Famotidine                       | Axid Capsule <sup>®</sup>  |
| Ranitidine                       | Axid Solution <sup>®</sup>   |
| Ranitidine syrup                 | Cimetidine Syrup   |
|                                  | Cimetidine Tablet  |
|                                  | Nizatidine   |
|                                  | Pepcid Oral Suspension <sup>®</sup>                                |
|                                  | Pepcid Tablet <sup>®</sup>   |
|                                  | Tagamet <sup>®</sup>   |
|                                  | Zantac Tablet <sup>®</sup>   |
|                                  | Zantac <sup>®</sup> syrup <i>no PA required for age &lt; 12yrs</i> |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Gastrointestinals: Proton Pump Inhibitors

### LENGTH OF AUTHORIZATIONS:

- Prilosec® OTC, if successful, may be continued with no limitations to duration of therapy
- Protonix® to be approved for 120 days (if 60-day trial of Prilosec® OTC fails)
- Non-preferred products to be approved for 120 days (with failure of both Prilosec® OTC and Protonix®)
- *For exceptions see criteria for “Proton Pump Inhibitors exception”*

1. Step one requires a therapeutic failure of a **60-day trial** of OTC Prilosec® (up to 40mg daily). For exceptions to this see criteria for “Proton pump inhibitors exception”.

Other things to consider when reviewing OTC Prilosec®

- Allergy to Omeprazole
- Contraindication to or drug-to-drug interaction with OTC Prilosec® (Omeprazole)
- History of unacceptable/toxic side effects to OTC Prilosec® (Omeprazole)
- Patient’s condition is clinically unstable; changing to OTC Prilosec® might cause deterioration of the patient’s condition.

Document details

2. If has failed step one then move to step two and the other preferred medication, Protonix® must be tried. If there is a therapeutic failure of no less than a **one-month trial** with Protonix® then may approve the requested medication for duration of 120 days.

Other things to consider when reviewing

Is there any reason the patient cannot be changed to Protonix®, Acceptable reasons include:

- Allergy to Protonix®
- Contraindication to or drug-to-drug interaction with Protonix®
- History of unacceptable/toxic side effects to Protonix®
- Patient’s condition is clinically unstable; changing to a medication not requiring prior approval might cause deterioration of the patient’s condition.

Document details

## Gastrointestinals: Proton Pump Inhibitors exceptions

**LENGTH OF AUTHORIZATIONS:** If an exception is met, approve desired product and make the duration for 1 year. Step therapy requirements detailed above do not apply.

### EXCEPTIONS

- Erosive Esophagitis
- Active GI Bleed
- Zollinger-Ellison Syndrome
- Greater than 65 years of age
- If Failed 120 day trial and is under the care of a Gastroenterologist and has Ruled out a nonsecretory Condition

Document details

See next page for specific drug lists.

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Virginia Medicaid Preferred Drug List, Effective January 1, 2008**

**Gastrointestinals: PPIs (see step edit)**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-preferred Drugs - PA Required</b>          |
|---|---|
| Protonix® <i>*(Pantoprazole)</i>        | Aciphex® <i>*(rabeprazole)</i>                    |
| Prilosec OTC® **                        | Nexium®   |
|   | Omeprazole <i>no PA req age &lt; 12yrs</i>        |
|   | Prevacid® caps <i>no PA req age &lt; 12yrs</i>    |
|   | Prevacid® susp <i>no PA req age &lt; 12yrs</i>    |
|   | Prevacid® solutab <i>no PA req age &lt; 12yrs</i> |
|   | Prilosec® Rx form                                 |
|   | Zegerid® Capsule                                  |
|   | Zegerid® effervescent tablet                      |
|   | Zegerid® susp Packet                              |
|   | <i>(Zegerid® OTC) *</i>                           |

**SPECIAL CONSIDERATION:**

Protonix® is a delayed release tablet and cannot be crushed or opened. For tubed patients or patients with swallowing difficulties omeprazole, Prevacid®, Prevacid Solutab®, Prilosec®, Nexium or Prevacid® granules (if oral administration) can be used. These Proton Pump Inhibitors may be opened and the intact granules may be mixed in apple sauce or orange juice and administered. Alternatively, the capsules may be opened and the granules may be dissolved in a small amount of sodium bicarbonate to form a compounded suspension for administration. The omeprazole will be the preferred agent for these circumstances and may be approved.

\*\*If therapy is for a child < 12 then Prevacid® Susp, Prevacid® solutab, Prevacid Caps no PA req age or Omeprazole will not require a PA ) If there has been a therapeutic failure on omeprazole or there is a clinical contraindication to omeprazole then another non-preferred agent may be approved.

Aciphex® is an extended release tablet and should not be opened or crushed.

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Growth Hormone Pediatrics

**Length of Authorization (pediatrics):** 1 year

**PEDIATRICS (18 years of age and under)**

**Clinical Criteria for Approval:**

Prescriber is an endocrinologist, nephrologists, infectious disease specialist or HIV specialist or one has been consulted on this case, the patient has open epiphysis and one of the following diagnoses

- Turner Syndrome
  - Prader-Willi Syndrome
  - Renal insufficiency
  - Small for gestational age (SGA) - including Russell-Silver variant and patient is < 2 years old
  - Idiopathic Short Stature (for request for renewal only **(a)** information is required to be approved)
  - Growth hormone deficiency (physician should provide the required information below)
  - Newborn with hypoglycemia and a diagnosis of hypopituitarism or panhypopituitarism.
- a. Height is more than 2 SD (standard deviations) below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age, or for children over two years of age, a decrease in height SD of more than 0.5 over one year; **AND**
- b. Growth hormone response of less than 10ng/ml to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine, or glucagon

**Requests for Renewal (pediatrics):**

- a. For renewal, a response must be documented. Patient must demonstrate improved/normalized growth velocity. (Growth velocity has increased by at least 2 cm in the first year and is greater than 2.5 cm per year), **AND**
- b. Patient height is less than 5' 6" for males or 5' 1" for females, and is more than 1 standard deviation (2") below mid-parental height (unless parental height is diminished due to medical or nutritional reasons).

**PDL CRITERIA**

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

Has there been a therapeutic failure after a reasonable therapeutic trial with use of **one** of the non-prior authorized agents? Document the details, and forward all of these requests to a clinical pharmacist

See **Growth Hormone for all groups for list of preferred/non-preferred**

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*



## Growth Hormone Adults

**Length of Authorization:** 1 year (Serostim<sup>®</sup> – 3 months)

**ADULTS (> 18 years of age)**

**Clinical Criteria for Approval:**

- Prescriber is an endocrinologist
- Diagnosis of growth hormone deficiency confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA);
- Cause of growth hormone deficiency is Adult Onset Growth Hormone Deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism, as a result of hypothalamic or pituitary disease, radiation therapy, surgery or trauma
- Other hormonal deficiencies (thyroid, cortisol or sex steroids) have been ruled out or stimulation testing would not produce a clinical response such as in a diagnosis of panhypopituitarism.
- **Zorbtive<sup>®</sup>**
  - Diagnosis of short bowel syndrome
- **Serostim<sup>®</sup>**
  - Diagnosis of AIDS Wasting or cachexia
  - Patient has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace<sup>®</sup> and Marinol<sup>®</sup>)
  - **Length of Authorization (Serostim<sup>®</sup> only):** 3 months initial; then 1 year.  
Renewal is contingent upon improvement in lean body mass or weight measurements.

**Requests for Renewal (adults)**

Renewal is contingent upon prescriber affirmation of positive response to therapy (improved body composition, reduced body fat, and increased lean body mass).

**PDL CRITERIA**

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. Has there been a therapeutic failure after a reasonable therapeutic trial with use of **one** of the non-prior authorized agents? Document the details, and forward all of these requests to a clinical pharmacist.

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Growth Hormone Adults & Pediatrics continued pg 3****Growth Hormones for all groups**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-preferred Drugs - PA Required</b> |
|---|--|
| Genotropin                              | Humatrope Cartridge                      |
| Norditropin Cartridge                   | Saizen Vial                              |
| Nutropin Aq Cartridge                   | Tev-Tropin                               |
| Nutropin                                | Humatrope Vial                           |
| Nutropin Aq Vial                        | Saizen Cartridge                         |
| Norditropin Nordiflex                   | Omnitrope                                |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Glaucoma Agents

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?  
Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug-to-drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
 Document clinically compelling information
2. The requested medication may be approved if both of the following are true:  
If there has been a therapeutic failure to no less than a **one-month trial** of at least **one** medication **within the same class** not requiring prior approval
3. The requested medications corresponding generic (if a generic is available) has been attempted and failed or is contraindicated

### Glaucoma Agents

#### Alpha 2 Adrenergic Agents

|                                |                      |
|--------------------------------|----------------------|
| Alphagan P® 0.1% & 0.15% drops | Alphagan® 0.2% drops |
| Brimonidine 0.2% drops         |                      |
| Iopidine® 0.5% & 1% drops      |                      |

#### Beta Blockers

|  |                                    |
|--|------------------------------------|
| Betaxolol 0.5% drops                     | Betagan® 0.25% & 0.5% drops        |
| Betimol® 0.25% & 0.5% drops              | Istalol® 0.5% drops                |
| Betoptic-S® 0.25% susp drops             | Ocupress® 1% drops                 |
| Carteolol 1% drops                       | Optipranolol 0.3% drops            |
| Levobunolol 0.25% & 0.5% drops           | Timoptic® drops 0.25% & 0.5% drops |
| Metipranolol 0.3% drops                  | Timoptic XE® 0.25% & 0.5% Sol-Gel  |
| Timolol maleate drops 0.25% & 0.5% drops |                                    |
| Timolol maleate 0.5 % Sol-Gel            |                                    |

#### Carbonic Anhydrase Inhibitors

|                       |  |
|-----------------------|--|
| Azopt® 1% drops       |  |
| Cosopt® 0.5%-2% drops |  |
| Trusopt® 2% drops     |  |

#### Prostaglandin Analogs

|   |                      |
|---|----------------------|
| Lumigan® 0.03% drops                        | Rescula® 0.15% drops |
| Travatan Z® drops                           |                      |
| Travatan® 0.0004% drops                     |                      |
| Xalatan® 0.005% drops <i>*(Latanoprost)</i> |                      |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Immunomodulators: Topical

**LENGTH OF AUTHORIZATION:** 1 YEAR

### CLINICAL CONSIDERATIONS:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?  
Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug-to-drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
 Document clinically compelling information
2. A PA may only be given for an FDA approved Diagnosis:
  - a. **Atopic dermatitis (a type of eczema) - FDA approved:**
    - **Elidel®:** mild to moderate for **ages > 2 years.**
    - **Protopic® 0.03%:** moderate to severe for **ages > 2 years.**
    - **Protopic® 0.1%:** moderate to severe for **ages > 18 years.**
  - b. All other diagnoses (off-label uses) are to be referred to a clinical pharmacist. **All requests** for all other diagnoses are to be denied.

**Critical information for review:** Black box warnings are in place for both products as well a requirement for a patient guide to be given with each product dispensed.

The FDA recommends that healthcare providers, patients and caregivers consider the following: (Updated from FDA site 8/29/07) \*\*

- Use Elidel and Protopic only as second-line agents for short-term and intermittent treatment of atopic dermatitis (eczema) in patients unresponsive to, or intolerant of other treatments.
- Avoid use of Elidel and Protopic in children younger than 2 years of age. The effect of Elidel and Protopic on the developing immune system in infants and children is not known. In clinical studies, infants and children younger than 2 years old treated with Elidel had a higher rate of upper respiratory infections than did those treated with placebo cream.
- Use Elidel and Protopic only for short periods of time, not continuously. The long term safety of Elidel and Protopic are unknown.
- Children and adults with a weakened or compromised immune system should not use Elidel or Protopic.
- Use the minimum amount of Elidel or Protopic needed to control the patient's symptoms. In animals, increasing the dose resulted in higher rates of cancer.

\*\*<http://www.fda.gov/cder/drug/infopage/protopic/default.htm>

\*\*[http://www.fda.gov/cder/drug/advisory/elidel\\_protopic.htm](http://www.fda.gov/cder/drug/advisory/elidel_protopic.htm)

### Topical Immunomodulators

| Preferred Drugs - PA Required | Preferred Drugs - PA Required |
|-------------------------------|-------------------------------|
| Elidel®                       |                               |
| Protopic®                     |                               |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Leukotriene Receptor Antagonists

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?  
Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug-to-drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approvalDocument clinically compelling information
2. If there has been a therapeutic failure to the agent not requiring prior approval, then may approve the requested medication.  
Document details

### Leukotriene Receptor Antagonists

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Accolate <sup>®</sup>            | Zyflo <sup>®</sup>                |
| Singulair <sup>®</sup>           | Zyflo CR <sup>™</sup>             |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Lipotropics

### LENGTH OF AUTHORIZATIONS: 1 year

#### General Guidelines:

Currently there are four classes of medications in the Lipotropics with three classes represented in the PDL. Each class has a different mechanism of action and acts on different components of total cholesterol

- Fibric acid derivatives-& Omega 3 agent
- HMG COA reductase Inhibitors
- Nicotinic acid derivatives
- Bile Acid Resins (*not included in VA PDL at this time*)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- Patient's condition is clinically unstable; changing to a medication not requiring prior approval might cause deterioration of the patient's condition.

Document clinically compelling information

2. If there have been therapeutic failures to no less than **one-month** trials of at least **one** medication not requiring prior approval, then may approve the requested medication.

Document details

3. If documented very high triglycerides of ( $\geq 500$  mg/dL) in adult patients. Then a PA for Omacor<sup>®</sup>/Lovaza<sup>®</sup> can be approved with out any specific preferred medication trials.

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See next pages for specific drug lists.

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Virginia Medicaid Preferred Drug List, Effective January 1, 2008**

**Lipotropics  
(Continued page 2)**

**Lipotropics – Fibric Acid Derivatives and Omega 3 agent**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-preferred Drugs - PA Required</b> |
|---|--|
| Antara <sup>®</sup>                     | Lovaza <sup>®</sup>                      |
| Gemfibrozil                             | Tricor <sup>®</sup>                      |
|   | Triglide <sup>®</sup>                    |

**Lipotropics – Niacin Derivatives**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-preferred Drugs - PA Required</b> |
|---|--|
| Niacor <sup>®</sup>                     |  |
| Niaspan <sup>®</sup>                    |  |

**Lipotropics – HMG CoA Reductase Inhibitors and Combinations (Statins)**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-preferred Drugs - PA Required</b> |
|---|--|
| Advicor <sup>®</sup>                    | Caduet <sup>®</sup>                      |
| Altoprev <sup>®</sup>                   | Crestor <sup>®</sup>                     |
| Simvastatin                             | Lipitor <sup>®</sup>                     |
| Lescol <sup>®</sup>                     | Mevacor <sup>®</sup>                     |
| Lescol XL <sup>®</sup>                  | Pravachol <sup>®</sup>                   |
| Lovastatin                              | Vytorin <sup>®</sup>                     |
| Pravastatin                             | Zocor <sup>®</sup>                       |

**Lipotropics - CAI**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-preferred Drugs - PA Required</b> |
|---|--|
| Zetia <sup>®</sup>                      |  |
|   |  |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

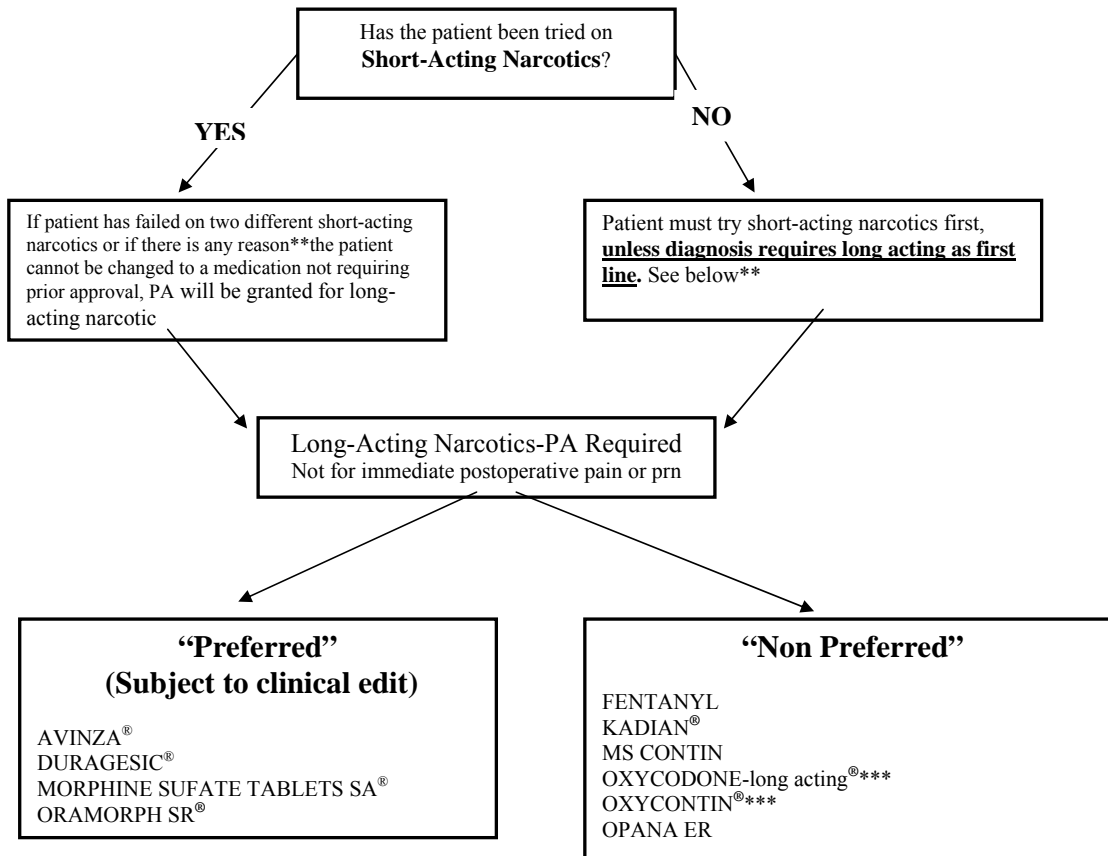
## Long Acting Narcotics – Step Therapy

### SHORT ACTING NARCOTICS (no PA required)

|                         |                           |       |
|-------------------------|---------------------------|-------|
| Butalbital Combinations | Methadone*                | Opana |
| Butalbital w/codeine    | Morphine-short acting     |       |
| Codeine                 | Nalbuphine                |       |
| Codeine w/APAP          | Oxycodone-short acting    |       |
| Codeine w/ASA           | Oxycodone w/APAP          |       |
| Hydrocodone             | Oxycodone w/ASA           |       |
| Hydrocodone w/APAP      | Oxymorphone               |       |
| Hydromorphone           | Pentazocine combinations  |       |
| Levorphanol             | Propoxyphene combinations |       |
| Meperidine              | Fentora                   |       |

*\*The use of methadone for pain should ideally be done in the context of an organized pain clinic, hospice or with assistance of local pain management experts, including health care providers or pharmacists, who have experience with methadone use.*

### Step-Therapy



*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*



## Virginia Medicaid Preferred Drug List, Effective January 1, 2008

**\*\*Step-Therapy is not required for those patients that have been stabilized on Long Acting Narcotics or need relief of moderate to severe pain requiring around-the-clock opioid therapy, for an extended period of time. Additional acceptable reasons include:**

- Allergy to medications not requiring prior approvals
- Contraindications to or drug-to-drug interaction with medications not requiring prior approval
- *If the patient has a diagnosis that is an approved indication for the medication that requires prior approval and this diagnosis is not an indication for the medications that do not require prior approval.*
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

**LENGTH OF AUTHORIZATIONS:** 6 months

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### **OxyContin\*\*\* / Oxycodone-long acting\*\*\*Guidelines**

1. Coverage is limited to those persons 18 years of age or older with a need for a continuous around-the-clock analgesic for an extended period of time for the management of moderate to severe pain.
2. There are no diagnosis restrictions here. The main objective is to verify appropriate use and the following items should be taken into consideration when reviewing an oxycontin request:
  - Dosing frequency greater than bid (tid for an identified, organized pain clinic or pain specialist)
  - Dosing using multiple small strength tablets as opposed to a single higher strength tablets
  - Odd quantities that would result in fractional dosing
  - Patient history of substance abuse
  - Frequent early refill attempts
  - Multiple request pertaining to lost medication
  - Short-term or prn use (oxycontin is not indicated for short-term or prn use)
  - Any suspicious use reported by pharmacies or physicians
  - A rapid increase in dosage
  - 80mg tablets are for opioid tolerant patients only
3. Reasons for denial:
  - Split tablets
  - Greater than tid dosing frequency
  - Concurrent use of other extended release opioids
  - Prn dosing

1997 medical society of Virginia and house of delegates guidelines Virginia code 54.1-2971.01 states:

**"In the case of a patient with intractable pain, the attending physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be deemed to be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes. Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this section."**

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## NSAIDs (Non-Steroidal Anti-inflammatory Drugs)

**LENGTH OF AUTHORIZATIONS:** 1 YEAR

- For COX II clinical edit see page 18

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. The requested medication may be approved if **both** of the following are true:

- If there has been a therapeutic failure to no less than a **one-month** trial of at least **two** medication(s) within the same class not requiring prior approval
- The requested medications corresponding generic (if a generic is available) has been attempted and failed or is contraindicated.

3. If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then document details and refer to a clinical pharmacist.

**ADDITIONAL INFORMATION TO CONSIDER**

- If the patient is allergic to one NSAID or aspirin, the patient may be allergic to other NSAIDs.

See next pages for specific drug lists.

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## NSAIDs (Non-Steroidal Anti-inflammatory Drugs)

### (Page 2)

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Diclofenac potassium             | Anaprox®                          |
| Diclofenac sodium                | Anaprox DS®                       |
| Diffunisal                       | Ansaid®                           |
| Etodolac                         | Arthrotec®                        |
| Etodolac SR                      | Cataflam®                         |
| Fenoprofen                       | Clinoril®                         |
| Flurbiprofen                     | Daypro®                           |
| Ibuprofen                        | Dolobid®                          |
| Indomethacin                     | Feldene®                          |
| Indomethacin SR                  | Flector patch                     |
| Ketoprofen                       | Indocin®                          |
| Ketoprofen ER                    | Indocin SR®                       |
| Ketorolac                        | Lodine®                           |
| Meclofenamate sodium             | Lodine XL®                        |
| Nabumetone                       | Mefenamic                         |
| Naproxen                         | Meloxicam                         |
| Naproxen sodium                  | Mobic®                            |
| Oxaprozin                        | Motrin®                           |
| Piroxicam                        | Nalfon®                           |
| Sulindac                         | Naprelan®                         |
| Tolmetin Sodium                  | Prevacid Naprapac®                |
|                                  | Naprosyn®                         |
|                                  | Orudis®                           |
|                                  | Oruvail®                          |
|                                  | Ponstel®                          |
|                                  | Relafen®                          |
|                                  | Tolectin DS®                      |
|                                  | Toradol®                          |
|                                  | Voltaren®                         |
|                                  | Voltaren XR®                      |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

**Ophthalmic Antihistamines/Mast Cell Stabilizers****LENGTH OF AUTHORIZATIONS:** 1 year

2. Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to product formulation (i.e. dyes or fillers). If an allergy to drug class, should question medication request.
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

3. If there has been a therapeutic failure to no less than a **three-day** trial of **one** medication within the same not requiring prior approval, then may approve the requested medication. Document details.**ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

**Ophthalmic Antihistamines**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-Preferred Drugs - PA Required</b> |
|---|--|
| Elestat drops®                          | Emadine drops®                           |
| Alaway OTC®                             | Zaditor RX drops®                        |
| Optivar drops®                          |  |
| Ketotifen Fumerate                      |  |
| Patanol drops®                          |  |
| Pataday drops®                          |  |
| Zaditor OTC drops®                      |  |

**Ophthalmic Mast Cell Stabilizers**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-Preferred Drugs - PA Required</b> |
|---|--|
| Alamast drops®                          | Crolom drops®                            |
| Alocril drops®                          |  |
| Alomide drops®                          |  |
| Cromolyn Sodium                         |  |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Ophthalmic Anti-inflammatory

**LENGTH OF AUTHORIZATIONS:** for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to product formulation (i.e. dyes, fillers). If an allergy to drug class, should question medication request.
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. If there has been a therapeutic failure to no less than a 3 **day** trial of **one** medication within the same not requiring prior approval, then may approve the requested medication. Document details.

### **ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

### **Ophthalmic Anti-Inflammatory**

| <b>Preferred Drugs - No PA Required</b> | <b>Non-Preferred Drugs - PA Required</b> |
|---|--|
| Acular drops®                           | Acular PF droperette®                    |
| Acular LS drops®                        | Ocufen drops®                            |
| Flurbiprofen Sodium                     |  |
| Nevanac drops Susp®                     |  |
| Voltaren drops®                         |  |
| Xibrom drops®                           |  |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Ophthalmic Fluoroquinolones

**LENGTH OF AUTHORIZATIONS:** for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to product formulation (i.e. dyes, fillers). If an allergy to drug class, should question medication request.
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication. Document details.

- Note diagnosis and any culture and sensitivity reports

3. If there has been a therapeutic failure to no less than a **three-day** trial of **one** medication within the same not requiring prior approval, then may approve the requested medication. Document details.

### **ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

### Ophthalmic Fluoroquinolones

| Preferred Drugs - No PA Required | Non-Preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Ciprofloxacin drops              | Ciloxan drops®                    |
| Ofloxacin drops                  | Ciloxan oint®                     |
| Quixin drops®                    | Ocuflox drops®                    |
| Vigamox drops®                   |                                   |
| Zymar drops®                     |                                   |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Oral Hypoglycemics

**LENGTH OF AUTHORIZATIONS:** 1 Year

1. Is there any reason the patient cannot be switched to a non-prior approved medication?

Acceptable reasons include:

- Allergy to the non-prior approved products in this class
- Contraindication or drug to drug interaction with all non-prior approved products
- History of unacceptable side effects

Document clinically compelling information

2. Has the patient tried and failed a therapeutic trial of thirty days with **one** of the non-preferred drugs **within the same class**? If so, document and approve the prior authorized drugs.

### Oral Hypoglycemics

| Preferred Drugs - No PA Required       | Non-preferred Drugs - PA Required |
|--|-----------------------------------|
| <b>Alpha-Glucosidase Inhibitors</b>    |                                   |
| Glyset®                                |                                   |
| Precose®                               |                                   |
| <b>Biguanides</b>                      |                                   |
| Metformin                              | Glucophage®                       |
| Metformin ER                           | Glucophage XR®                    |
|  | Glutmetza®                        |
|  | Fortamet®                         |
|  | Riomet® suspension                |
| <b>Biguanide Combination Products</b>  |                                   |
| Avandamet®                             | Glucovance®                       |
| Glipizide/metformin                    | Metaglip®                         |
| Glyburide/metformin                    |                                   |
| <b>Meglitinides</b>                    |                                   |
| Starlix® <i>*(Nateglinide)</i>         | Prandin®                          |
| <b>Thiazolidinediones</b>              |                                   |
| Actos®                                 | Avandryl®                         |
| Avandia®                               | Duetact®                          |
| Actoplus Met®                          |                                   |
| <b>Second Generation Sulfonylureas</b> |                                   |
| Glipizide                              | Amaryl®                           |
| Glipizide ER                           | Diabeta®                          |
| Glyburide                              | Glucotrol®                        |
| Glyburide micronized                   | Glucotrol XL®                     |
| Glimepiride                            | Glynase®                          |
|  | Micronase®                        |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Osteoporosis Agents – Bisphosphonates

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medication not requiring prior approval
- Contraindication to or drug-to-drug interaction with medication not requiring prior approval
- History of unacceptable/toxic side effects to medication not requiring prior approval

Document clinically compelling information

2. Has the patient tried and failed a therapeutic trial with a preferred drug **within the same class**? If so, document and approve the prior authorized drug.

### Bisphosphonates

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Actonel®                         | Actonel with calcium®             |
| Fosamax®                         | Boniva®                           |
| Fosamax® solution                |                                   |
| Fosamax plus D®                  |                                   |

*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*



## Phosphodiesterase 5 Inhibitors Pulmonary Arterial Hypertension

**LENGTH OF AUTHORIZATIONS:** 1 year

**Diagnosis** of Pulmonary Hypertension in patients 18 years of age or older is required.

The requested medication may be approved if both of the following are true:

- The prescribing physician is a pulmonary specialist or cardiologist.
- Client has documented Pulmonary Arterial Hypertension and will be followed by the prescribing physician.

Document clinically supporting information

**Contraindications where the PA should not be approved:**

- Concurrent use of nitrates (e.g., nitroglycerin)
- Hypersensitivity to Sildenafil.

| PD5 Inhibitor                    |                                   |
|----------------------------------|-----------------------------------|
| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
| Revatio®                         |                                   |
|                                  |                                   |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Sedative/ Hypnotics

**LENGTH OF AUTHORIZATIONS:** Length of the prescription (up to 3 months)

2. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

3. **To receive a non preferred benzodiazepine** there must have been a therapeutic failure to no less than a **one-month** trial of at least **one benzodiazepine** not requiring prior approval, then may approve the requested medication.

Document details

4. **To receive a preferred non benzodiazepine** there must have been a therapeutic failure to no less than a **one-month** trial of a benzodiazepine (*step edit*)

5. **To receive a non preferred non benzodiazepine** there must have been a therapeutic failure to no less than a **one-month** trial of

- First a benzodiazepine (*step edit*)
- Second a therapeutic failure to not less than a **one-month** trial of Rozerem®
- Then may approve the requested medication.

Document details

6. If a request for Ambien® is received for a pregnant patient, approve the Ambien® for the duration of the prescription or the duration of the pregnancy (whichever is shorter).

7. For **patients age 65 and older**, Rozerem®, Ambien® or Lunesta® may be approved after a trial of trazodone (duration = at least one month). It is not necessary for patient's  $\geq 65$  to try a benzodiazepine if they have had a trial of trazodone.

See next pages for specific drug lists.

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Sedative/ Hypnotics (Page 2)

**Sedative Hypnotics (Benzodiazepine)**

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Estazolam                        | Dalmane <sup>®</sup>              |
| Flurazepam                       | Doral <sup>®</sup>                |
| Temazepam                        | Halcion <sup>®</sup>              |
| Triazolam                        | Prosom <sup>®</sup>               |
| Chloral hydrate Syrup            | Restoril <sup>®</sup>             |

**Sedative Hypnotics (Non-Benzodiazepine) See step edit**

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Rozerem <sup>®</sup> **          | Ambien <sup>®</sup>               |
| Zolpidem                         | Ambien CR <sup>®</sup>            |
|                                  | Lunesta <sup>®</sup>              |
|                                  | Somnote <sup>®</sup>              |
|                                  | Sonata <sup>®</sup>               |
|                                  | *(Tovalt ODT)                     |

\*\* Must meet Step edit as noted above to receive Rozerem<sup>®</sup>

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*

## Urinary Antispasmodics

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

2. If there has been a therapeutic **failure to at least a one-month trial of at least one medication** not requiring prior approval, then may approve the requested medication.

### Urinary Antispasmodics

| Preferred Drugs - No PA Required | Non-preferred Drugs - PA Required |
|----------------------------------|-----------------------------------|
| Detrol LA <sup>®</sup>           | Detrol <sup>®</sup>               |
| Enablex <sup>®</sup>             | Ditropan <sup>®</sup>             |
| Oxybutynin Tablet                | Ditropan XL <sup>®</sup>          |
| Oxybutynin Syrup                 | Oxybutynin ER                     |
| Oxytrol <sup>®</sup> Transdermal |                                   |
| Sanctura <sup>®</sup>            |                                   |
| Vesicare <sup>®</sup>            |                                   |

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*\*New generic, brand, or dose formulation anticipated, will be non-preferred pending review*